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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/26/2005

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EXAMINER

LAO, MARIALOUIA

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,564	Applicant(s) AMANO ET AL.	
	Examiner LOUISA LAO	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/14/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The supplemental IDS is acknowledged.

Response to Arguments

2. Applicant's arguments filed 2/14/08 have been fully considered but they are not persuasive, see below. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. The rejection of claims 1-6 is maintained under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (US5756838, US`838 *equivalent to WO9522405 in IDS*) in view of Ishizaki et al. (US5274146, US`146 *equivalent to EP0544455 in IDS and JP5170780 in specification*) and Ishizaki et al. (US5324861, US`861).

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5. Applicants' claims are drawn to a method for producing an optically active carboxylic acid formula [2], comprising the step of subjecting an unsaturated carboxylic acid formula [1] in water or a mixed solvent of water and a water-insoluble organic solvent in the presence of a sulfonated BINAP-Ru complex represented by the formula [3]: $[\text{RuX}(\text{arene})\{(\text{SO}_3\text{M})_2\text{-BINAP}\}]\text{X}$ wherein X represents a chlorine atom, a bromine atom or an iodine atom, arene represents a benzene or an alkyl-substituted benzene, M represents an alkaline metal atom, and BINAP represents 2,2'-bis(diphenylphosphine)-1,1'-binaphthyl to an asymmetric hydrogenation. The sulfonated BINAP-Ru complex catalyst used can be recovered and reused as an aqueous solution.

6. US'838 teaches (Abstract) a method for conducting asymmetric reactions on prochiral unsaturated bonds contained within a compound using the water soluble chiral sulfonated 2,2'-bis(diphenylphosphino)-1,1'-binaphthyl organometallic catalyst. In columns 15-16, Example 9 US'838 teaches that hydrogenation of 2-(6'-methoxy-2'-naphthyl) acrylic acid using various combinations of water or water with organic solvent, where US'838 disclosed that the water content of the SAP catalyst is highly dependent on the water content in the SAP catalyst. While in column 18 lines 36-44, US'838 teaches that hydrogenation of 2-(6'-methoxy-2'-naphthyl)acrylic acid was accomplished using a redissolved catalyst solution from a used SAP (supported aqueous phase organometallic catalyst) in methanol, where the ruthenium complex is stable in the SAP configuration. US'838 teaches that the performance of the hydrated SAP catalyst is bounded by the intrinsic enantioselectivity limit of the ruthenium sulfonated BINAP catalyst in water. In column 18 lines 47-54, US'838 teaches the recycling and reuse of the SAP catalyst, where there is a consistency in performance of the recycled catalyst.

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7. US`838 is different from instant claims where asymmetric hydrogenation of the unsaturated carboxylic acid uses the catalyst, where the phenyl portions of the BINAP are sulfonated, which in contrast to the instant sulfonated BINAP, which is sulfonated on the naphthyl rings. US`861 and US`146 differ from the instant starting material for asymmetric reaction, where the former have an olefin, ketone or imine relative to the instant unsaturated carboxylic acid.

8. However, US`861 and US`146 on the other hand teach asymmetric hydrogenation reactions using an alkali metal sulfonate-substituted binaphthyl-phosphine transition metal complex, with the catalyst formula and substituents therein recited. In column 7 lines 15-22 of both US`861 and US`146, teaches that the starting material was added to the aqueous layer (containing the organometallic catalyst complex) under the same reaction conditions as the fresh catalyst to reuse and recycle said catalyst, since said catalyst can be repeatedly used.

9. At the time of the invention, one of ordinary skill in the art wanting to use the asymmetric hydrogenation of unsaturated carboxylic acids of US`838 would have found it obvious to employ the catalysts of the cited prior art references, US`861 and US`146. The combination of the teachings of US`838 suggests that specific features of the invention may be combined with other features of US`861 and US`146, as in the use of different form of the catalyst. In this case, the sulfonated BINAP catalysts of US`861 and US`146 teach a method for synthesizing similar catalysts (see columns 5-6 Example 1 of US`861 and US`146)(i.e. sulfonated naphthyl BINAP) and its use in asymmetric hydrogenation. Therefore, it would have been obvious to modify the method of US`838, such as by using an equivalent catalyst of US`861 and US`146, since one of ordinary skill in the art at the time of the invention, as compelled by norms of practice, would

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look for alternate and equivalent materials through routine experimentation, as dictated by cost and availability with a reasonable expectation of success.

10. Absent the showing of criticality and unexpected beneficial results, the recitation of alternate substituents is an optimization step that is within the normal undertaking of one of ordinary skill in the art at the time of the invention and would not require any inordinate degree of experimentation. The claim would have been obvious because the substitution of one known element for another, *such as sulfonated BINAP catalyst in lieu of alkali metal sulfonate-substituted binaphthyl-phosphine transition metal complex*, would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Optimizing such processes is *prima facie* obvious because an ordinary artisan would be motivated to use known processes from the art to make the process more efficient or explore economical advantages over the other. Merely modifying the process conditions is not a patentable modification absent a showing of criticality. In re Aller, 220 F.2d 454, 105 U.S.P.Q. 233 (C.C.P.A. 1955).

- Applicants argue that (a) the structure of the ligand in US'848 differs from that of the ligand of the instant catalyst.

However, this was recognized by the discussion presented in the Office Action mailed 8/15/07; whereupon *sulfonated BINAP catalyst in lieu of alkali metal sulfonate-substituted binaphthyl-phosphine transition metal complex* in an asymmetric hydrogenation of a carboxylic acid is obvious. It would have been obvious to an artisan, because the substitution of one known element for another, *such as sulfonated BINAP catalyst in lieu of alkali metal sulfonate-substituted binaphthyl-phosphine transition metal complex*, would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

- Applicants argue the merits of the instant catalyst, in terms of reacting as a homogeneous catalyst, high efficiency, dissolution in the reaction solution and facile separation as an aqueous solution for recycle and re-use.

However, these attributes were recognized by the discussion presented in the Office Action mailed 8/15/07; as taught by the cited references.

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- Applicants contend that the improved optical purity of the ensuing end-product is not trivial, given the use of the instant catalyst.

However, it is the norm of an artisan to engage in experimentation, including the use of equivalent materials, to reach an optimum quality of his desired end-product. Absent a showing of criticality and unexpected beneficial results, the purity obtained is the end result of routines of optimization. The claims would have been obvious because “a person of ordinary skill has good reason to pursue the known options within his grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.”

- Applicants further argue that the secondary references US`146 and US`861 are not drawn to the same starting material.

However, US`838 teaches unsaturated carboxylic acid which is equivalent to the instant starting materials; whereupon the secondary references were relied upon for the obvious substitution of catalyst, i.e. sulfonated BINAP catalyst in lieu of alkali metal sulfonate-substituted binaphthyl-phosphine transition metal complex.

Therefore, Applicants' arguments *in toto* are unpersuasive.

11. No claims are allowed.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to LOUISA LAO whose telephone number is (571)272-9930. The examiner can normally be reached on Mondays to Thursdays from 8:00am to 8:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

04102008

Louisa Lao

Examiner

Art Unit 1621

/Porfirio Nazario-Gonzalez/
Primary Examiner, Art Unit 1621